

Notice of Allowability

Application No.

10/822,938

Examiner

Karen Cochrane Carlson, Ph.D.

Applicant(s)

HSIAO ET AL.

Art Unit

1656

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to the papers filed November 5, 2007.
2. ☒ The allowed claim(s) is/are 54-59, 61-74, 76-78 and 80-82.
3. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) ☐ All b) ☐ Some* c) ☐ None of the:
 1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

* Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.
THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

4. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
 5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
 - (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
 - 1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
 - (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.
- Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

1. ☒ Notice of References Cited (PTO-892)
2. ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3. ☐ Information Disclosure Statements (PTO/SB/08),
Paper No./Mail Date _____
4. ☐ Examiner's Comment Regarding Requirement for Deposit
of Biological Material

5. ☐ Notice of Informal Patent Application

6. ☐ Interview Summary (PTO-413),
Paper No./Mail Date _____

7. ☒ Examiner's Amendment/Comment

8. ☒ Examiner's Statement of Reasons for Allowance

9. ☒ Other + 2nd 892 from 4-20-2006 with
a date provided for the
citation

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on November 5, 2007 has been entered.

Claims 1-53, 60, and 75 have been cancelled. Claims 54-59, 61-74, and 76-82 are currently pending. NOTE that Claim 78 has been presented twice and the claims must be renumbered according to Rule 126.

Benefit of priority is set to April 11, 2003.

An **Examiner's Amendment** to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Amy Purcell on January 23, 2008.

Examiner's Amendments to the Claims:

The numbering of claims is not in accordance with 37 CFR 1.126 which requires the original numbering of the claims to be preserved throughout the prosecution. When claims are canceled, the remaining claims must not be renumbered. When new claims are presented, they must be numbered consecutively beginning with the number next following the highest numbered claims previously presented (whether entered or not).

Misnumbered claim 78 been renumbered as Claim 79. Accordingly, the subsequent claims must also be renumbered.

The Allowed Claims are:

1-53. (Cancelled)

54. (Previously Presented) A method of producing collagen monomers comprising:

(a) contacting collagen-containing tissues with microorganisms wherein the collagen-containing tissues are obtained from one or more of mammals, aquatic animals, and avian animals, and wherein the microorganisms are bacteria or fungi;

(b) allowing the microorganisms to ferment the collagen-containing tissues;

(c) solubilizing the fermented tissues by the addition of an acidic solution and an enzyme preparation;

(d) precipitating the collagen monomers; and

(e) obtaining the precipitated collagen monomers, wherein the precipitated collagen product comprises collagen monomers weighing at least 10% of the weight of the total collagen in said collagen product.

55. (Previously Presented) The method of claim 54, wherein the enzyme preparation comprises pepsin.

56. (Previously Presented) The method claim 54, wherein the precipitation is carried out by the addition of salt.

57. (Previously Presented) The method of claim 54, wherein the microorganisms are grown for more than 24, 48 or 72 hours before fermenting the collagen-containing tissues.

58. (Previously Presented) The method of claim 54, wherein fermentation is performed with agitation and aeration.

59. (Previously Presented) The method of claim 54, wherein the collagen product comprises collagen monomers weighing at least 50% of the weight of the total collagen in said collagen product.

60. (Cancelled)

61. (Previously Presented) The method of claim 54, wherein the microorganisms comprise generally regarded as safe (GRAS) microorganisms.

62. (Previously Presented) The method of claim 54, wherein the microorganisms are bacteria.

63. (Previously Presented) The method of claim 62, wherein the bacteria are Gram positive.

64. (Previously Presented) The method of claim 63, wherein the bacteria are of the genus *Bacillus*.

65. (Currently Amended) The method of claim 54, wherein the mammals are porcine or bovine.

66. (Previously Presented) The method of claim 54, wherein the aquatic animals are fish or shark.

67. (Previously Presented) The method of claim 54, wherein the avian animals are chickens.

68. (Previously Presented) A method of producing collagen monomers comprising:

(a) contacting Gram (+) bacteria belonging to the genus *Bacillus* in a fermenter with collagen-containing tissues, wherein the collagen-containing tissues are obtained from one or more of mammalian, aquatic, or avian animal sources;

(b) allowing the bacteria to ferment the collagen-containing tissues at about 10% w/v to about 40% w/v in the fermenter;

(c) solubilizing the fermented tissues at about 1% w/v to about 50% w/v in an acidic solution of about 0.5M acetic acid (pH 3.0) with pepsin provided at about 0.2% w/v to about 5% w/v at low temperatures;

(d) adding salt to the acidic solution sufficient to precipitate collagen and keeping it undisturbed overnight; and

(e) obtaining the precipitated collagen monomers,

wherein the precipitated collagen product comprises collagen monomers weighing at least 10% of the weight of the total collagen in said collagen product.

69. (Previously Presented) The method of 68, wherein the collagen-containing tissues are fermented in the fermenter for about 18 hours to about 48 hours.

70. (Previously Presented) The method of claim 69, wherein the collagen-containing tissues are fermented at about 10% w/v in the fermenter for about 24 hours.

71. (Previously Presented) The method of claim 69, wherein the acidic solution is about 3% w/v of about 0.5M acetic acid (pH 3.0) with pepsin provided at

about 0.4% w/v to about 2% w/v and further comprising stirring for not more than about 48 hours when solubilizing the fermented tissues in the acidic solution.

72. (Previously Presented) The method of claim 71, wherein the mammalian source is porcine or bovine.

73. (Previously Presented) The method of claim 70, wherein the acidic solution is about 3% w/v of about 0.5M acetic acid (pH 3.0) with pepsin provided at about 1% w/v and further comprising stirring for about 48 hours when solubilizing the fermented tissues in the acidic solution.

74. (Previously Presented) The method of claim 73, wherein the avian source is chicken.

75. (Cancelled)

76. (Previously Presented) The method of claim 68, wherein the low temperatures is at about 4°C.

77. (Previously Presented) The method of claim 54, wherein the collagen product comprises collagen monomers weighing at least 50% of the weight of the total collagen in said collagen product.

78. (Previously Presented) The method of claim 54, wherein the collagen product comprises collagen monomers weighing at least 80% of the weight of the total collagen in said collagen product.

~~78.~~ 79. (Cancelled)

~~79~~, 80. (Previously Presented) The method of claim 54, wherein the microorganisms are fungi.

~~80~~, 81. (Currently Amended) The method of claim ~~79~~ 80, wherein the microorganisms are yeast.

~~81~~, 82. (Previously Presented) The method of claim 62, wherein the bacteria are Gram negative.

The following is an **Examiner's Statement of Reasons for Allowance**: The Declaration of Seah June Nam has been considered. In the declaration, Nam demonstrates that four more different bacteria comprising both Gram negative and positive bacteria, can be used to make collagen monomers according to the method claimed. With the disclosure in the specification that Gram positive bacteria and yeast can be used according to the method claimed, it is more likely than not that microorganisms can be used to make collagen monomers as set forth in the method claimed.

The prior art of record does not teach or suggest the method claimed to make collagen monomers. For example, Gaier et al. (USP 5645,877, issued June 8, 1997) teaches the use of lactobacillus to digest/ferment collagenic material to made fermented food products. Bickley (GB 2 189 492, published October 28, 1987) teaches the production of soluble collagen from hides using lactobacteria followed by an acid solution wash. Bickley does not teach to further subject the hides to an enzyme preparation such as pepsin. Therefore, the claims are allowable over the art of record.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the

issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Karen Cochrane Carlson, Ph.D. whose telephone number is 571-272-0946. The examiner can normally be reached on 7:00 AM - 4:00 PM, off alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Kathleen Kerr Bragdon can be reached on 571-272-0931. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.


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PRIMARY EXAMINER